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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,346	11/12/2003	Steven F. Bolling	ORQIS.007A	6824

20995 7590 02/05/2009  
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EXAMINER
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KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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02/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/706,346	<b>Applicant(s)</b> BOLLING ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-21 and 86-114 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-21 and 86-114 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/02/2008, 01/22/2009</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

The Examiner acknowledges the reply filed 10/02/2008 in which claims 7 and 108 were amended and new claims 110-114 were added. Currently claims 3-21 and 86-114 are pending for examination in this application. The Examiner also acknowledges the new sheet drawing (Figure 23E) filed 11/10/2008 and the amended specification filed 10/02/2008.

### ***Claim Objections***

Claims 4, 7, 10 and 99 are objected to because of the following informalities: Regarding claims 4, 7, 10 and 99, the independent claim (7) references "a plurality of discharge openings" yet several of the dependant claims (2, 10, 99) and the subsequent body of the independent claim only reference a single discharge opening. Appropriate correction is required.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) that were submitted on 10/02/2008 and 01/22/2009 are partly in compliance with the provisions of 37 CFR 1.97. Examiner has not considered some documents because IDS contains citations that are not US patent documents or publicly available publications. If Applicant wishes to cite documents that are NOT US patent documents, they must listed in the Non-Patent literature section and be provided to Examiner and the relevant information identified by Applicant as per MPEP 609 and 37 CFR 1.97. Accordingly, the examiner is considering part of the information disclosure statements (see attached).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-13, 86-94, 96, 99-104 and 107-114 rejected under 35 U.S.C. 103(a) as being unpatentable over Uthmann (USPN4,385,631) in view of Watkins et al. (3,995,617) or O'Keefe et al. (USPN6,921,378).

Regarding claims 3-13, 86-94, 96, 99-104 and 107-114, Uthmann discloses a catheter (Figure 1) capable of being used for percutaneously discharging blood within a patient's vasculature, the cannula comprising: a pump, a main cannula portion (10) comprising a blood flow lumen extending therethrough; and a tapered tip portion extending from the main cannula portion (18), a plurality of discharge openings (21) spaced radially around the tip; an additional lumen (lumens 11, 12) with an inlet (19)

distal to the tip and extending through the tip section capable of being used to withdrawn blood from the patient's vasculature or as a guidewire lumen.

Uthmann meets the claim limitations as described above except for the redirecting members.

However, Watkins et al. teaches a heart assist method and catheter.

Regarding claims 3-13, 86-94, 96, 99-104 and 107-114, Watkins et al. discloses a catheter (Figure 1) capable of being used for percutaneously discharging blood within a patient's vasculature, the cannula comprising: a pump (col 3, ln 45-65, col 5, ln 1-10), a main cannula portion (50) comprising a blood flow lumen extending therethrough; and a tapered tip portion extending from the main cannula portion (area of 55a-55c), a plurality of discharge openings (50d) spaced radially around the tip; and a plurality of redirecting members (55a-55c) each comprising expandable members configured to expand under pressure of the blood flow directed through the discharge openings such that at least a portion of the expandable member (55a-55c) is spaced from the discharge openings by a greater amount than prior to such expansion, the expandable member (55a-55c) presenting a continuous concave redirecting surface when expanded comprising a different material (col 3, ln 40-55), with the redirecting members configured to direct blood flow through the discharge openings proximally along the cannula (Figure 2) (Figures 1-5). Watkins et al. further discloses that the redirecting members (55a-55c) are collapsible to cover the discharge opening (Figure 4a) with different perimeters during expansion and contraction and is actable to pre-defined shape

(Figure 4b) with an additional lumen (56a) extending through the tip capable of being used to withdrawn blood from the patient's vasculature or as a guidewire lumen.

Additionally, O'Keefe et al. teaches an anti-reflux drainage device and method.

Regarding claims 3-13, 86-94, 96, 99-104 and 107-114, O'Keefe et al. discloses a catheter body (133) with a distal opening (near 146) with collapsible cover (158) member (Figure 1F).

At the time of the invention, it would have been obvious to incorporate the valve covers of Watkins et al. or O'Keefe et al. to the system of Uthmann in order to prevent reverse flow through the discharge openings and meter the outflow through the openings. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Watkins et al. (cols 1-2) or O'Keefe et al. (cols 1-2).

### ***Claim Rejections - 35 USC § 103***

Claims 15-21 are rejected under 35 U.S.C 103(a) as being unpatentable over Uthmann (USPN4,385,631) in view of Watkins et al. (3,995,617) or O'Keefe et al. (USPN6,921,378) in further view of Hedge et al. (6,231,543). The modified Uthmann et al. meets the claim limitations as described above except for a guidewire and seal in the distal end thereof.

However, Hedge et al. teaches a single lumen balloon catheter.

Regarding claims 15-17 and 19, Hedge et al. teaches a catheter (10) that includes a guidewire (18) and a guidewire lumen (16) with multiple guidewire seals and

plugs (30, 42, 44) that minimize blood flow through the lumen and can plug the lumen when a guidewire is not present in the lumen (Figures 4-6B).

At the time of the invention, it would have been obvious to add the guidewire and lumen of Hedge et al. to the modified system of Uthmann et al. in order to aid in catheter guiding and tracking during a surgical procedure. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hedge et al. (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 95, 97-98 and 105-106 are rejected under 35 U.S.C 103(a) as being unpatentable over the Uthmann (USPN4,385,631) in view of Watkins et al. (3,995,617) or O'Keefe et al. (USPN6,921,378).

Regarding claims 95 and 97-98, the modified Uthmann et al. discloses the claimed invention except for the specific sizes and shapes of the redirecting member with respect to the discharge openings. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Watkins et al. to the shapes and sizes as claimed in order to adjust the flow through the device absent specific criticality, since it has been held the variations in shape were a matter of choice and only involves routine skill in the art. See *In re Dailey*, 357 F.2d 669, 149 USPQ (CCPA 1966).

Regarding claims 105-106 discloses the claimed invention except for re-directing comprising silicone of a hardness of less than 15 A scale durometer. It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of modified Uthmann et al. with the material as claimed by Applicant in order to adjust the proper flow through the discharge openings, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

### ***Response to Arguments***

Applicant's arguments with respect to claims 3-21 and 86-114 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. KOHARSKI whose telephone number is (571)272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 1/31/2009

/Christopher D Koharski/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763